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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,223	12/10/2001	Artur Mitterer	20695C-002100US	9005

7590 06/17/2003

KEVIN L. BASTIAN, ESQ.
TOWNSEND AND TOWNSEND AND CREW
8TH FLOOR
TWO EMBARCADERO CENTER
SAN FRANCISCO, CA 94111-3834

EXAMINER
LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/17/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/006,223	MITTERER ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *1-9, 13-25* is/are withdrawn from consideration.

5)☒ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-12 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet* .

Continuation of Attachment(s) 6). Other: Requirement for Information under 37 CFR 1.105.

DETAILED ACTION

Election/Restrictions

1. Claim1-9, and 13-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

Claims 1-26 are pending in the application. Claim 26 was added in paper number 11, this claim falls within the elected Group II of the restriction Groups. Therefore, claims 10-12, and new claim 26 are under consideration in the application.

2. Applicant's election with traverse of Group II in Paper No. 11 is acknowledged. The traversal is on the ground(s) that there is no undue search required in the examination of the various claimed inventions. This is not found persuasive because, as indicated in the restriction requirement, the various inventions read on a number of different products and methods that would each require a separate search. For example, a search for a virus would not yield the necessary results required for the examination of the claims to the purified Streptomyces griseus trypsin (SGT).

With respect to the elected invention, SGT, the most closely related group is group I, which identifies methods of isolating SGT from PRONASE. As SGT can be either isolated or produced by other means, the search for the protein itself is not necessarily coextensive with the search for the method.

In view of the requirement for various non-coextensive searches for each of the different inventions, the requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

3. The information disclosure statement submitted on November 12, 2002 (the IDS) is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Specification

4. The use of the trademark PRONASE has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

5. Claims 10 and 26 are objected to because of the following informalities: the Applicant uses the term SGT without first identifying what the acronym stands for. It is suggested that the applicant amend these two independent claims to read on purified preparations of "Streptomyces griseus trypsin (SGT)." Appropriate correction is required.

6. Claim 12 is objected for reference to the composition with the tradename PRONASE without writing the word in uppercase letters. Although the use of trademarks is permissible in

patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Koo et al., J Microbiol Biotech 8(4) :333-40. Claim 10 describes SGT preparations with specific activity of 25000 U/mg. The Koo reference teaches the purification of SGT from Pronase with a result yields of 62672 and 31155 U/mg. See, page 336 (Table 2), and page 337 (Table 3). Thus, the reference meets the claim limitations, and therefore anticipates the claim. The reference does not disclose the purity of the trypsin preparation.

It is noted that claim 12 further limits the claimed preparation to embodiments purified by a particular method. However, determination of the patentability of product by process claims is based upon the product itself, not the process used to make it. See, MPEP §2113; and In re Thorpe, 227 U.S.P.Q. 964, at 966 (Fed. Cir. 1985). Koo therefore anticipates claim 12, despite not teaching the identified method of purification, because it teaches the claimed preparation.

9. Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Kasai et al. J Chromatography 597: 3-18 (of record in the IDS). This claim reads on purified preparations of trypsin of at least 95% purity. Such a composition is described on page 5, right column, of the reference.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koo et al., in view of Kasai. Claim 11 describes a SGT preparation with a specific activity of at least about 25 x10^3 U/mg, and a purity of 95%. The teachings of Koo and Kasai are disclosed above. Koo, while disclosing an SGT preparation with the claimed specific activity, does not disclose the purity level of the preparation. However, it would have been obvious to one of ordinary skill in the art to improve the purity level of that preparation by further purifying it using the method of Kasai.

Conclusion

12. No claims are allowed.

13. The following prior art references are made of record and are considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

Tashiro et al., Agric Biol Chem, 45(2): 519-21 (1981). Tashiro teaches a SGT preparation with a specific activity of 155 BAEE units/mg protein.

Jurasek et al., Can J Biochem, 49: 1195-1201 (of record in the IDS). The reference discloses the achieved specific activity as being equivalent to 102% of the PRONASE specific activity. According to the teachings on page 520 of the Tashiro reference identified above, a 155 BAEE U/mg is 10 times the specific activity of PRONASE, which would indicate that whatever the specific activity of PRONASE in U/**ml** are, they are approximately 15 U/**mg** protein. Thus, if the Jurasek SGT preparation has only 102% of the specific activity of PRONASE, it does not have a specific activity of 25 x 10^3 U/mg.

Wu et al., Biomedical Chromatography, 10: 228-32. This reference teaches a purified trypsin preparation with a specific activity of 28 U/mg protein. However, the reference does not appear to be describing SGT, as the reference does not indicate that the trypsin is being isolated from PRONASE.

Ito et al., J Chromatography, 333: 107-114. This reference teaches an method of isolating SGT from a sample using a gel chromatography with benzamidine as the affinity moiety.

Kim et al., Biomed Biophys Res Comm, 181: 707-13. This reference teaches the protein and nucleotide sequence of SGT. This reference also teaches that SGT may be purified through the same systems used for bovine trypsin.

Hatanaka et al., Biochemica et Biophysica Acta, 832: 274-79. This reference teaches that SGT may be more effective in some forms of hydrolysis than bovine trypsin.

14. **This Office action has an attached requirement for information under 37 CFR 1.105.** A complete reply to this Office action must include a complete reply to the attached

requirement for information. The time period for reply to the attached requirement coincides with the time period for reply to this Office action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner
June 6, 2003

James C. Housel 6/16/03

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Requirement for Information under 37 CFR 1.105

1. Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

2. The information is required to complete the background description in the disclosure by documenting the differences indicated by the applicant between the specific activities of trypsin as indicated by the Applicant and the prior art. The Applicant has taught purified SGT with specific activities of between 16 to 46 x 10^3 U/mg protein, and claimed purified SGT preparations with specific activities of at least about 25 x 10^3 U/mg protein. In one instance, the application discloses that a specific activity of 16 x 10^3 was achieved through ion exchange chromatography. However, the closest art found by the Examiner, or provided by the Applicant, teaches maximum specific activities that appear to be less than those disclosed by the Applicant by a factor of 2. See e.g., Tashiro et al., Agric Biol Chem, 45(2): 519-21 at 520 (1981); and Olafson et al., Biochemistry 14(6): 1161-67 at 1162 (each of which discloses SGT specific activities in the range of about 150 units/mg). Furthermore, Tashiro et al. also discloses that the purified SGT disclosed therein was purified by ion exchange chromatography, just as was the SGT fraction in Example 1 of the present application. The Examiner therefore requests information to account for the 2 factor difference in units/mg that appear to separate the results disclosed in the present application, and those disclosed in the art using like methods of purification.

The Examples by the Applicant wherein the resultant SGT specific activities were 16.5 x 10^3 and 19 x 10^3 (pages 18-20, Tables 1 and 2, respectively) each appear to have used methods known in the art, but which did not, in the prior art known to the Examiner, teach such high specific activities. See, Tashiro (ion exchange chromatography), Shimura and Kasai (J Biochem 92:1615-22), and Kasai (J Biochem 78:653-62). Each of these reference teach similar modes of purifying SGT, or trypsin, but none of them achieve specific purities within 2 factors of those disclosed by the Applicant. If the Applicant has other references teaching the use of these methods of SGT purification, or other references disclosing results using known methods with comparable results to the two results identified above, such information is requested in addition to that which was requested above.

It is noted that the Examiner has rejected claim 10 (which reads on an SGT purification with a specific activity of at least about 25 x 10^3 U/mg protein) over the Koo et al reference. However, this reference calculated the specific activity of trypsin using a different hydrolysis target (N-α-benzoyl-DL-arginine-ρ-nitroanilide) from that used in the other references identified above and in the Examples in the application (each of which used BAEE). Thus, absent further explanation indicating to the contrary, the Examiner is assuming that this distinction accounts for the difference between the results of Koo and those of the other references.

3. In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the

requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure.

4. The fee and certification requirements of 37 CFR 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR 1.105 are subject to the fee and certification requirements of 37 CFR 1.97.

5. The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained will be accepted as a complete reply to the requirement for that item.

6. This requirement is an attachment of the enclosed Office action. **A complete reply to the enclosed Office action must include a complete reply to this requirement**. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

JAMES HOUSEL 6/16/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600